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The MI-HEART Project

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Among various factors associated with increased mortality of coronary heart disease, excessive patient delay (PD) in seeking medical care during acute myocardial infarction (AMI) has been shown to play an important role [1]. Two thirds of the delay from onset of symptoms to treatment is patient related, and one quarter is hospital related [2]. Clinical studies have repeatedly shown that most patients do not seek medical care for 2 hours or more after symptom onset for AMI [3–7]. Their prolonged PD precludes or limits the rational utilization of potentially lifesaving procedures, as timely delivery of optimal therapy for AMI is crucial [8]. It is well documented that a significant reduction in PD would increase the proportion of patients eligible to receive reperfusion or interventional therapies and possibly also reduce the out of hospital deaths [5,8].

Many factors contributing to an increase in PD, such as denial of symptoms of AMI, self-treatment, asking a family member or physician for advice [9,10], inappropriate coping mechanism, hampering health beliefs, and so forth, have been identified [5,11]. Modifiable factors include somatic and emotional awareness [12,13], perceived threat [14,15], health beliefs [10,16], knowledge about AMI symptoms [16,17], and relevant decision making [18,19]. Self-treatment and asking a family member or physician for advice are noteworthy modifiable factors demonstrated to delay arrival to the emergency by an hour or more. Nonmodifiable factors associated with increased delay pertain to patient history, the context in which symptoms arise, the symptoms presenting during AMI, and sociodemographic factors.

PD can be costly considering that the first hour immediately after a heart attack is the crucial time when thrombolytic therapy can significantly improve the victim's chances for survival. Although the efficacy of thrombolytic therapy has been known for years, only a fraction of those experiencing an AMI receive this treatment. If time can be reduced from the onset of heart attack symptoms to allow for the delivery of appropriate therapy, lives could be saved and long-term cardiac damage avoided. It is difficult to imagine a more striking example of how information, particularly information provided using innovative technologies, can save lives.

The Myocardial Infarct Health Education Aimed at Rapid Therapy (MI-HEART) Project, funded by the National Heart Alert Program (NHAAP), used such novel technologies to examine ways in which a clinical information system can favorably influence the appropriateness and rapidity of decision making in patients suffering from symptoms of AMI. When designing the MI-HEART project, it was understood that persons who experience symptoms need to be informed on how best to respond. However, when patients experience symptoms that may be indicative of a heart attack, their reaction is very complex. Developing an intervention to modify this response required an understanding of the process so that important variables that contribute to the decision are identified. It is only then that information can be effectively *tailored* to each individual's psychological state on the factors that contribute to patient decision making. Tailoring information to an individual's characteristics, needs, and interests increases the personal relevance of intervention messages, which in turn results in an increase in the effectiveness of an intervention [20–22].

Therefore in phase one of the MI-HEART project, we developed a conceptual model that allowed us to isolate and measure specific factors that contribute to patient decision making. In phase two of the project, we conducted a randomized trial that examined the following hypothesis, based on the model and using the existing clinical information system at New York Presbyterian Hospital: *educational tools that make use of information from a patient's medical record will exert a favorable influence on measurable parameters of the patient's cognitive processes, suggesting that they are more likely to perform appropriately in an acute situation*.

Development of the Conceptual Model

The model for patient decision-making incorporates several behavior models (Health Belief Model [23], Social Cognitive Theory [24]) and includes somatic and emotional awareness, perceived threat, expectations of symptoms, self-efficacy, and outcome expectations to explain the response of an individual to his or her symptoms. We used formal behavioral theories, an extensive review of published empirical investigations, and qualitative methods to guide the selection of these factors. Table 19.1 provides a summary of variables in our model, their theoretical origin, and a brief description.

Based on this set of variables, we assembled our model [25], shown in Fig. 19.1, by expanding on previous medical and health behavior models used to reduce delay in seeking care for AMI [26,27]. Whereas most previous research examined variables separately, our model presents a framework to consider how these variables might be interrelated in explaining the act of decision within the context of moderating variables.

According to our model, we can consider patients to be in some cognitive state prior to an educational intervention and in some second state following the intervention.

Table 19.1. Modeling patient response to AMI summary of variables.

Variable	Description
Somatic and emotional awareness	Individuals ability to identify inner experiences of emotion and body sensations
Perceived threat[a] (vulnerability/seriousness)	Individuals perception of his or her risk of getting an AMI Feelings concerning the extent of harm that could result from an AMI
Expectations of symptoms	Individuals ability to match the signs and symptoms to their concept of how a heart attack should feel
Response efficacy	Individuals estimate that their behavior will lead to a certain outcome
Self-efficacy	Individual's confidence in his or her ability to take action by performing the behaviors necessary
Symptom context	Consultation with others (spouse, co-worker); decision to consult a physician, time and place of symptom onset
Sociodemographic/ health history	Demographic and health history type variables, e.g., history of diabetes, angina, age, sex, etc.

[a] Based on the Health Belief Model, the combination of vulnerability and seriousness is labeled *perceived threat*.

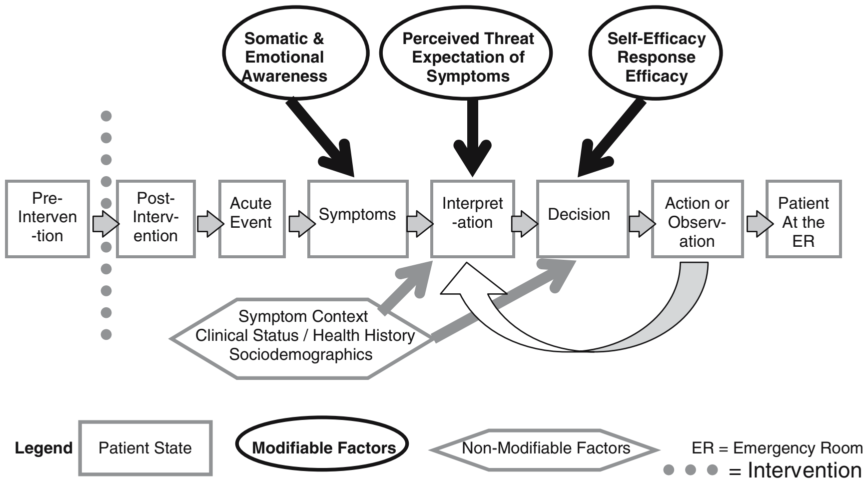

FIGURE 19.1. Model of patient response to an AMI.

When an actual event occurs (the physiological episode), external stimuli (e.g., chest pain) cause the patient to enter the **Symptom Phase**. Symptoms from the episode may be experienced with varying degrees of sensitivity related to the *somatic and emotional awareness* levels of the individual. Low somatic and emotional awareness are characteristics that tend to diminish the perception and/or reporting of cardiac symptoms, thereby leading to excessive delay in seeking medical attention [28]. Published studies concur that subjects who report higher levels of bodily and emotional awareness were more likely to seek treatment for symptoms of AMI earlier [29]. Patients unable to identify their symptoms are not likely to attend to them and may respond only when the symptoms cannot be ignored. Accordingly, the disruptive qualities of symptoms will determine whether the patient pays attention to or ignores symptoms. Providing that symptoms are attended to, the individual enters into the **Interpretation Phase**. In this phase, symptoms attended to are ascribed to a cause by the individual, for example, indigestion, nothing important, or cardiac. This labeling process requires that the signs and symptoms attended to be put within an understandable framework. Few patients are able to determine rapidly that their signs and symptoms represent a heart attack. Rapid self-diagnosis is more likely to occur when the individual is able to match these signs and symptoms to their concept of how a heart attack should feel [30]. We label this variable *expectation of symptoms* in our model referring to the matching of signs and symptoms to the patient's preconceived prototype of what symptoms should feel like. Knowledge of chest pain is recognized as an important heart attack symptom; however, knowledge of the complex constellation of heart attack symptoms is deficient in the US population, especially in socioeconomically disadvantaged and racial and ethnic minority groups [31].

Knowledge alone is insufficient to motivate action, and may be insufficient to cause the patient to ascribe familiar symptoms to AMI. In addressing other cognitive and emotional consequences of symptoms attended to in the previous stage, the individual may perceive a *threat* from the prototypical meaning of symptoms. Because the act of decision process involves the labeling of these deviant patterns of symptoms, that is, assessment of the imminent health threat, our model proceeds to adopt the value-expectancy notion contained within the Health Belief Model suggesting that the notion of threat has its greatest impact in this initial decision [32]. The Health Belief Model suggests that the labeling of deviant health patterns and response to symptoms is influenced by the person's beliefs about how susceptible he or she is to a heart attack or other heart trouble, how serious the illness is, and how effective specific actions will be in reducing the perceived threat. It is the individual's *perception of vulnerability* to heart attack coupled with the individual's *perceptions of seriousness* of heart attack that combine to form belief about an imminent health threat. Perceived levels of threat affect the ability to correctly ascribe symptoms to a cardiac origin. If the threat is perceived as irrelevant or insignificant, then there is no motivation to take action. If the interpretations of the symptoms are as noncardiac, the action taken may be inappropriate. Perceptions of threat compiled by the individual suggest that the individual employs two types of memories: episodic, which are autobiographic memories from the individual's past experiences and include affective responses, and semantic memories which reflect more abstract and conceptual information about symptoms provided by healthcare associations, for example, the American Heart Association's warnings of a heart attack [33]. For some individuals, arousal from the threat is so intense that they become unresponsive to the symptoms. These individuals may present with a presumably silent AMI, or be among those who die outside the hospital with sudden cardiac deaths. The Interpretation Phase ends when the individual has a label or hypothesis as to the meaning of the symptoms and proceeds to the **Decision Phase** to address the demands in terms of developing an action strategy. Once into the Decision Phase, *response efficacy*, that is, beliefs about the effectiveness of the recommended response, and *self-efficacy*, that is, beliefs about one's ability to perform the recommended response and confidence in labeling symptoms [34], determine whether the patient will become motivated to accept or reject the proposed action plan. Within this study "accept" defines the decision to go to the emergency room for medical care whereas "reject" defines the decision not to go to the emergency room. High perceived efficacy (i.e., people feel able to perform an effective recommended response and confident that they are responding correctly) coupled with high perceived threat (i.e., people believe they are vulnerable to a significant threat) promote the "accept" response.

The development of the conceptual model was an essential first phase to guide the development of a tailored technology-based program to reduce patient delay. By isolating and explaining the reasons why people delay, we were able to design tailored and theoretically grounded strategies, resulting in a more effective intervention and evaluative tools that better affect patient decision-making.

The next phase two was directed at three specific accomplishments: creation of tailored educational messages, development of a computer-based system for delivering the messages, and a pilot study to measure the impact of messages.

Creation of Tailored Messages

The importance of creating tailored messages cannot be underscored enough. Prior research consistently demonstrates that tailored messages have a significantly greater effect on patients' behavior than generic messages [20,35–38]. Tailored messages are information intended to reach one specific person, based on characteristics unique to that person. It is information technology that allowed us to deliver the tailored messages through ubiquitous technology windows. These seamless communication channels enabled the recipients of our project to be reached with patient-specific messages using a one-by-one technique.

To create the tailored messages, it was necessary to collect and retrieve information for each individual on each variable contained in the cognitive model. At New York Presbyterian Hospital (NYPH), existing clinical information systems provided this capability for some variables. Additional patient data on the decision-influencing variables specified in our model not contained in the patient medical record were collected for our project using an online tailoring questionnaire.

While similar in design to a tool used to collect baseline data in a research study, the distinguishing feature of the tailoring questionnaire is the close-ended nature of the questions. In order to create all possible tailored messages before the assessment takes place, the response choices to each question must be known. There is benefit to abstracting data from the medical record when it exists because it reduces user burden, the time it will take for an individual to complete the questionnaire. MI-HEART participants received the online assessment questionnaire immediately after they logged on to the Web site, and were blocked from education content until all questions are answered.

The assessment questionnaire provided the framework for developing tailored messages. Because questions in the assessment questionnaire were developed to address the most important variables underlying patient decision making, the process was fairly straightforward. Managing the process involved the following steps: (1) write down each question contained in the assessment tool; (2) for each assessment question, list all its response choices; and (3) create unique content that would be appropriate for a person who gave each particular response to the assessment question. Response items for each question in the assessment tool then guided the development of educational strategies. To illustrate, one series of questions measured self-efficacy, and the response item was calculated as "low." Content was then designed to enhance self-efficacy by showing a graphic of a person similar to the user successfully performing the desired behavior. Skill building exercises and clearly elucidating the model users' success and skill acquisition were other strategies used to enhance self-efficacy. This type of learning, referred to as vicarious experience [39], is effective because visualizing people similar to oneself perform successfully typically raises efficacy beliefs in observers that they themselves possess the capability to master comparable activities. They persuade themselves that if others can do it, they too have the capabilities to raise their performance.

To increase outcome expectations, educational content was designed to demonstrate the relationship between the behavior and outcome and provided opportunities for users to experience specific outcomes as a result of the decision he or she has made. In the MI-HEART project, we used the process of *microtailoring* [40] to enhance the individualization of content by allowing an even greater amount of tailoring to occur in the messages themselves. Table 19.2 shows this tailoring methodology related to *expectation of symptoms*. *The expectation of symptoms* variable is defined as a person's ability to match the signs and symptoms to his or her concept of how a heart attack should feel. We used microtailoring for this variable because we know that certain characteristics of an individual may affect the types of signs and symptoms experienced. A description of this reasoning follows. Because heart attack symptoms may differ among persons with varying characteristics, the message content for this variable would be most relevant to each individual if it varied to match these characteristics. The decision as to what are the relevant characteristics was made using clinical

Table 19.2. Tailoring of messages with regard to expectation of symptoms.

	Patient profile								
		No Angina				Angina			
	No	More than two risk factors				Regardless of risk or no risk factors			
Nitroglycerin	Regardless	No	No	Yes		No	Yes	No	Yes
COPD	Regardless	No	Yes	No	Yes	No	No	Yes	Yes
Expectation of symptoms:									
Low	Message A	Message B	Message C	Message D	Message E	Message F	Message G	Message H	Message I
High	Message J	Message K	Message L	Message M	Message N	Message O	Message P	Message Q	Message R

judgment, standardized guidelines [41], and published research. The following considerations were used.

First, angina was regarded as a relevant characteristic because the symptom sets for patients with angina that could be warning signals for AMI are different than for the general population. Persons with angina or more than two cardiovascular disease (CVD) risk factors need to be aware of symptoms that may lead to unstable angina. Second, foreknowledge of chronic obstructive pulmonary disease (COPD) and CVD risk factors were regarded to be relevant characteristics, as persons with this condition are likely to experience unstable angina and angina equivalent such as shortness of breath, symptoms with potential to be confounded with the symptoms of COPD. Third, having an active prescription for nitroglycerine was regarded as a relevant characteristics because these individuals need to be informed that shortness of breath and chest pain that does not go away after taking nitroglycerine are considered to be warning signals as specified by the AMA. Fourth, scoring high or low on the expectation symptom variable itself was regarded to be a relevant characteristic because the framing and content of the message for persons with high levels must be designed specifically to avoid redundancy, while content for persons with low levels must be provided in detail. Thus, Table 19.2 distinguishes 18 messages based on a combination of the relevant characteristics [42].

The distinguishing feature enabled by Web technology is that it is possible to deliver a tailored mix of educational content directed simultaneously at motivation, beliefs, and skills—the multitude of determinants that affect a single behavior. Because we know that behavior change does not come about by providing a single uniform message, this feature has strong advantages over mass communications that are directed to everyone but no one in particular. Even individuals who need to make similar behavior changes are likely to differ on factors that influence their health behaviors. One individual may not feel at risk for developing a specific disease and thus may not perceive the need to be screened for that disease. This individual should have different content than someone who avoids the screening procedure because he or she fears finding out that he or she has the disease. It should also be noted that while tailoring has distinct functionality well suited to facilitate behavior change, developers need to carefully consider that even the benefits of tailoring interventions depend heavily on which kinds of behavioral determinants and individual characteristics are targeted. Sophisticated tailoring to weak or irrelevant determinants and individual characteristics will yield poor results.

Development of the Web-Based System for Delivering the Messages

Developing the Web-based system for delivering the messages required that a wide number of issues be addressed including user interface, security, database, and clinical trial management software.

User Interface

A dedicated Web portal, *www.mi-heart.com*, provided the access to the MI HEART messages. We spent a great deal of time developing and testing the user interface to ensure that it would be usable by a wide variety of patients, including those who might have chronic medical conditions such as arthritis (of the hands) and diabetes mellitus (with visual impairment). The user interface consisted of left buttons that trigger sub-buttons on the top of the screen. The center of the screen contained the tailored or nontailored educational material that was dynamically generated to correspond with the participant's group assignment in the randomized trial. The two-level hierarchy of buttons was required to provide "oversized accessible text sizes" on the buttons and limiting the information overload. Test users were videotaped during an extensive usability trial of all sections of the site and corrections to the design were conducted accordingly.

Security

Although no identifying data were available to users of the system, users' health data were shown in messages given to the tailored users. We therefore sought an intermediate level of authentication, using an ID and password. A "cookie" maintained the active session parameters and timed out after 10 minutes without user-initiated actions.

Database

The application consisted of one Access database (miheartdb.mdb) containing several distinct tables. TblUser contained the "study group identification" (tailored IT, non-tailored IT, non-tailored paper), while tblUser_Answer contained the answers of the patients to the tailoring questionnaires. The tailored messages for symptoms and actions were contained in the knowledge-base: cfsymptom2.mdb. It consisted of several tables interoperating according to 14 observations of the past history to produce 212 different guidelines. The other tailored components of the education were programmed as independent Coldfusion files evoked according to the absence, the presence, or the unavailability of one observation of the patient history. They consisted of individualized text, images, and sound tracks. The sound tracks contained individualized recommendations from physicians. A Web-based instrument for prediction of coronary heart disease risk was implemented according to the Framingham algorithm and messages were tailored to the patient according to the calculations.

Clinical Trial Management Software

A clinical trial management and administration module was developed to enroll and monitor the progress of enlisted patients. This component also provided valuable data to analyze usage between the trial groups. Multiple alerts and progress reports were made available throughout the project.

The Pilot Study to Measure the Impact of Messages

We describe the pilot study that was conducted in the final phase of the MI-HEART project with particular attention to the issues and caveats that may be useful to others embarking on a similar effort. The pilot study utilized a three-group randomized controlled design with pre- and post-intervention measures to determine the impact of the tailored messages. Following consent, all participants completed on online tailoring questionnaires and were then randomized into one of three groups: (1) tailored Web-based, (2) nontailored Web-based, or (3) nontailored paper-based. After completing the questionnaire, participants in the Web-based intervention groups had access to the intervention online. The paper-based intervention group received the educational materials by mail.

Participants were recruited from physicians' offices, advertisements, online resources, and promotional materials, for example, brochures and flyers. Potential participants interested in the study were sent a letter asking them to provide consent and consent from their physician. Physicians were also asked to confirm eligibility according to predetermined AMI risk criteria.

Baseline Data

Of the participants who enrolled in the study ($N = 94$), most were male (71%), married (77%), Caucasian (89%), with college or professional/postgraduate degrees (68%). The mean age was 57 years (SD = 10 years), 20% had yearly incomes between $50,000 and $74,000, and 35% had yearly incomes over $75,000. Fewer than 20% reported their health as excellent, 44% good, and 21% fair or poor. Thirty-five (35%) had had a heart attack, with a total of 60% told by a physician that they have a heart condition. Seventy-eight percent (78%) reported being told by a doctor or other health professional that their blood cholesterol is high, 70% were told that their low-density lipoprotein (LDL) or "bad" cholesterol level was high.

When asked, "If you had arm pain or numbness, shortness of breath, and sweating, how likely would you:

	Very likely
Contact spouse, friend, co-worker	63%
Contact physician	49%
Call 911	36%

Alternatively when asked, if you had chest pain, how likely would you:

Contact spouse, friend, co-worker	42%
Contact physician	34%
Call 911	31%

More often participants reported they would contact their spouse, friend, or co-worker when experiencing arm pain or numbness than if they had chest pain. Interestingly, more would contact their physician or call 911 with arm pain or numbness compared to what they would do if they experienced chest pain.

Changes in Self-Efficacy Scores

We have reported to date on one key construct contained in our model: self-efficacy [43]. Results of the randomized controlled study show trends in improved self-efficacy scores for all groups at 1-month follow-up, with sustained significant increases in scores only for the Web-based tailored intervention. According to our hypothesis, we anticipated that the tailored intervention would more favorably influence self-efficacy scores; however, new questions arise as to why the tailored intervention was the only group to sustain the effect at 3 months.

Analysis of "Hit-Count"

The Web-based delivery of our intervention allowed us to look at the usage logs to determine if there were differences between tailored and nontailored groups in the frequency the system was used. Usage was determined by "hit-count," the number of times the user selected a specific Web page to view. Note that the user could have performed many actions on one specific Web page, for example, print the contents of the page, scroll, and select audio clip. In this analysis, a repeated action on a given Web page still counts as one. The mean "hit-count" in the tailored groups was significantly higher than in the nontailored group, 21.8 and 12.4, respectively ($t = 2.09$, $p < .005$).

Discussion

Results of a randomized controlled study show trends in improved self-efficacy scores for all groups at 1-month follow-up, with sustained significant increases in scores only for the Web-based tailored intervention. According to our hypothesis, we anticipated that the tailored intervention would more favorably influence self-efficacy scores; however, new questions arise as to why the tailored intervention was the only group to sustain the effect at 3 months.

One possible explanation could be related to exposure. The logs on "hit-count" show that use of the tailored intervention was significantly greater when compared to the nontailored Web group. Of course, we have little to say about the paper-based group, as these data were not logged.

Previous studies have already alluded to reasons why tailored interventions are more effective than nontailored or generic type information. Because tailoring provides each person only the information selected for his or her characteristics, the messages contain less redundant information. People are therefore more likely to pay attention to the essential relevant information. Attention to the message is of essential importance for the health message to have an impact. Few previous studies were able to assess usage as we have done in this study, because most have used a paper-based delivery system. Based on the data we report here, exposure as defined as "hit-counts" may shed light as to why tailored interventions have a greater impact. One plausible explanation is that tailored interventions may not only increase attention, but also increase the cognitive effort that people are willing to invest in reading, comprehending, and processing a message.

Implications of Lessons Learned and Future Directions

The number of participants we recruited to the study was fewer than we had planned for. Although the final number recruited enabled data analysis to yield significant impact on selected outcome measures, the main caveat here is that even well researched and developed systems can and will be underutilized. An information resource that provides knowledge on health issues, particularly health promoting issues that are generally not the main concern of most intended users, requires thoughtful interventions to overcome low motivation. One possible solution is to intertwine the health promoting technology into everyday life patterns and other applications as much as possible. Bringing the user into incidental contact with the intervention may motivate interest in a health-promoting topic that may otherwise be of low salience.

A second issue relates to the digital divide. Our participants were primarily Caucasian, male, and well educated. Although we attempted to address many issues of access including developing the educational content to an appropriate literacy level, we faced what appeared to be downright resentment by individuals we attempted to recruit but were unwilling to participate because they were antagonized by yet another resource moving onto the Web. These participants may have had a computer with Internet access at home or at a nearby library. Their concerns, however, extended beyond the hard-wire access and their unease prevented them from reaching the point where they could appraise the usefulness of the content. The caveat here is for developers of new technologies to build into their interventions theoretical and empirically tested methods and implementation planning frameworks that account for the social and cultural factors of the digital divide, not just the technical factors [44,45].

The MI-HEART project required the development of three software components: a customizable user interface, an application for producing tailored messages, and a system for managing and monitoring research subject data. Each of these components has been designed to be reusable for other purposes and current projects are under way, or proposed, that will make use of them.

Acknowledgments. This work has been supported by National Library of Medicine Contract (NO1-LM-3534), and NLM Training Grant LM07079.

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